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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,300	10/23/2008	Michael Wagener	3968-179	4066

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
11/09/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,300	WAGENER ET AL.	
	Examiner	Art Unit	
	K Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *36-48* is/are pending in the application.

5a) Of the above claim(s) *43 and 47* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *36-42, 44-46 and 48* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 8/24/2011 wherein claims 36, 38 and 45 have been amended and claim 48 is newly added.

2. Claims 36-42, 44-46 and 48 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 8/24/2011 regarding the rejection of claims 36-42 and 44-46 made by the Examiner under 35 USC 112, second paragraph have been fully considered and they are found persuasive. This rejection has been overcome in view of Applicants arguments.

4. Applicants arguments filed 8/24/2011 regarding the rejection of claims 36-42, 45 and 46 made by the Examiner under 35 USC 103(a) over Terry (US 7820284) in view of Vissing et al. (US 7157145) have been fully considered but they are not found persuasive and is **MAINTAINED** for the reasons of record in the office action mailed on 8/24/2011.

5. In regards to the 103(a) rejection, Applicant asserts the following:

A) Because Terry suggests that their hydrophilic transport control layer is to provide increased patient comfort, decreased tissue irritation and increased antimicrobial effectiveness teaches away from the use of silicon. Moreover, Applicant points to the polymer of Vissing being hydrophobic. Thus, they cannot be properly combined as the properties required by Terry do not overlap.

6. In response to A, the Examiner is not persuaded by Applicant arguments. The Abstract of Vissing teaches the use of various polymers comprising at least 22-27% silicon, 25-50% oxygen and 25-50% carbon (see abstract). An exemplified polymer having such a composition is hexamethyldisiloxane which is used in Examples 1 and 2 (of Vissing) as a plasma polymer coating layer. The Examiner notes that the same polymer, hexamethyldisiloxane, is used by Applicant in their disclosed examples as their transport layer (see Example 1, for instance) wherein it's stated that the antimicrobial layer is "coated with a hydrophilic plasma polymer (transport control layer)." It is not clear to the Examiner why Applicant is alleging that the polymers of Vissing are hydrophobic while simultaneously using the very same plasma polymers of Vissing and describing it as hydrophilic. According to Applicants own specification and description hexamethyldisiloxane is a hydrophilic polymer. Thus, the combination of Terry and Vissing would result in a transport layer possessing a hydrophilic layer as evidenced by Applicants own description of the polymers used by Vissing as hydrophilic.

7. Applicants arguments filed 8/24/2011 regarding the rejection of claim 44 made by the Examiner under 35 USC 103(a) over Terry (US 7820284) in view of Vissing et al. (US 7157145) in further view of Burrell et al. (US 6333093) have been fully considered but they are not found persuasive and is **MAINTAINED** for the reasons of record in the office action mailed on 8/24/2011.

8. In regards to the 103(a) rejection, Applicant asserts the following:

B) The rejection over Terry in view of Vissing and Burrel should be withdrawn for the reason cited under A above.

9. In response to B, the Examiner respectfully disagrees. Applicant is directed to the Examiners response to assertion A at paragraph 7.

Maintained Rejections, of Record (Claims 36-42, 45, 46) and New Rejections, Necessitated by Amendment (claim 48)

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 36-42, 45, 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry (US 7820284; filed 12/3/2001) in view of Vissing et al. (US 7157145; filed 6/28/2002).**

13. Terry teaches microbe-resistant medical devices wherein an antimicrobial substrate is coated with an outer non-antimicrobial polymeric surface. The antimicrobial substrate comprises antimicrobial particles which can be metals and metal salts, oxides and complexes having oligodynamic properties, such as aluminum, antimony, bismuth, cerium, copper, gold, iridium,

magnesium, mercury, palladium, platinum, silver, tin and zinc and their salts, oxides, complexes and mixtures thereof (see column 3, lines 60-65; see instant claims 39 and 41). The size of the antimicrobial metallic particles is preferably less than about 3 microns (40 nanometers) (see column 4, lines 1-5; see instant claims 40). The overcoat is to be a polymeric substance which is to be hydrophilic (see column 4, lines 55-60; see claim 48).

14. The medical device of Terry is comparable to the instant claims as follows:

15. Because the medical device comprises at least two substances (i.e. the antimicrobial substrate and the non-antimicrobial polymeric surface) the device is considered to read on a layered material (as required by instant claim 36). The medical device clearly meets the limitation of being 'a medical product' claim 46 as well.

16. The antimicrobial substrate reads on a biocide layer having a biocidal active agent (component a) of claim 36. The species of antimicrobial agents taught by Terry read on those required by claims 39 and 41. The preferred size of the antimicrobial metallic particles (40 nanometers) anticipates the size range required by claim 40.

17. The overcoat is considered to read on a transport control layer covering the biocide layer (component b) of claim 36).

18. The medical device of Terry differs from the instantly claimed invention in that they fail to teach the transport control layer has thickness and porosity adjusted to release an antimicrobial and non-cytotoxic quantity of the biocidal agent from the biocide layer through the transport control layer, nor that the transport control layer is a plasma polymer wherein the transport control layer has a silicon content of 20 to 60%, a carbon content of 10 to 30% and an oxygen content of 30 to 50% (such as hexamethyldisiloxane).

19. Vissing teaches an article comprising a substrate and a plasma polymer comprising at least 22 to 27% silicon, 25 to 50% oxygen and 25 and 50% carbon wherein the polymer is applied to the surface of the substrate (see abstract; meeting the limitations of instant claims 36 and 42). It's taught that the plasma polymer can be applied to surfaces to impart a smooth and easy to clean surface (see column 2, lines 15-20). The plasma polymer may have a thickness of between 1 nm and 1,000 nm (see column 4, lines 40-45) this range encompasses the claimed range. It has been held that in cases where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (thereby meeting the limitation of instant claim 45). Examples 1 and 2 of Vissing use hexamethyldisiloxane as their plasma polymer layer. According to Applicants own specification (see Example 1, for instance), hexamethyldisiloxane is a hydrophilic polymer thereby meeting the limitation of instant claim 48.

20. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Terry so as to replace the hydrophilic polymer outercoat with the plasma polymer layer of Vissing for the purpose of imparting the device of Terry with a smooth and easy to clean surface. One would have been motivated to modify the device of Terry so as to replace the hydrophilic polymer outercoat with the surface plasma polymer of Vissing as doing so would impart a smooth and easy to clean surface which is desirable for medical devices. Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results is indicative of obviousness.

21. With respect to the requirement that the transport control layer has a gas permeability for oxygen (O_2) which is preferably in the range from 500 to 700 (cm^3 bar)/(day m^2), this is a property of the polymer having the instantly claimed silicon, oxygen and carbon content. As Vissing teaches a polymer which has silicon, oxygen and carbon content within the range of the instantly claimed (and specifically hexamethyldisiloxane- which is exemplified in Applicants' own specification, too), it'd be expected that it too would have overlapping O_2 permeability. Therefore, modification of the medical device of Terry to substitute the hydrophilic polymer outercoat layer with the easy-to-clean plasma polymer layer of Vissing would have been *prima facie* obvious, and the resulting medical product reads on the medical product of instant claims 36-42, 45 and 46.

22. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

23. **Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Terry (US 7820284; filed 12/3/2001) in view of Vissing et al. (US 7157145; filed 6/28/2002) as applied to claims 36-42, 45, 46 and 48 above, and further in view of Burrell et al. (US 6333093; published 12/25/2001).**

24. Terry and Vissing fail to teach the biocide layer has a mean thickness of 5-100 nm.

25. Burrell teaches wound dressings having antimicrobial coatings. The dressing may comprise different layers having antimicrobial activity. Exemplified antimicrobial agents include silver, gold, platinum, copper, bismuth and zing. The thickness of the layer comprising the

antimicrobial is to be greater than 60 nm thick (see column 8, lines 40-45; see instant claim 44). Thus, antimicrobial layers having a thickness between 5-100 nm are commonly employed in the art.

26. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Terry, Vissing and Burrell such that the antimicrobial layer of Terry would possess a thickness of 60 nm with a reasonable expectation in providing a layer suitable for the storage and release of antimicrobial metal particles. One would have been motivated to employ such a thickness as the prior art teaches that such thickness are useful for containing and releasing the antimicrobial active. That is, one would have a reasonable expectation for success in imparting biocidal benefit wherein the structure of Terry and Vissing is modified such that the thickness of the antimicrobial layer is about 60 nm. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
November 2, 2011

/Allison M. Ford/
Primary Examiner, Art Unit 1653